SECTION III

In Section III, the Working Group discusses six options for a National Materials Program structure. The options were developed through discussions with and comments from stakeholders and reflect the combined expertise of the Working Group members.

Section III begins with a brief description of each option followed by a table comparing the six options. Next a written comparison summarizes some key considerations. Following the summary, each option is discussed in depth, starting with the Current Program, which is used as the base case for comparison, and continuing through the range of options.

Options for a National Materials Program

Options for a National Materials Program were examined by the Working Group after considering discussions with and comments from stakeholders. In this report, the following six options were evaluated, beginning with the current program, which is used as a base case.

1. **Current Program**	Current NRC and Agreement State programs remain in effect. No policy changes are involved. This is the "Base Case" used by the Working Group for comparison of the other options.
2. **Independent States**	NRC has jurisdiction over federal facilities, areas of exclusive federal jurisdiction, and over certain quantities of special nuclear material. NRC does not provide regulatory oversight of materials programs. "Agreement States" as such do not exist; however, states could regulate materials based on state needs and priorities.
3. **Minimum NRC Involvement**	NRC may reduce efforts and resources from the current level to a minimal program by making changes to policies concerning implementation of program elements. States continue to become Agreement States and NRC maintains oversight function. Certain elements of a radiation protection program, such as performing inspections, are not directly specified in the AEA, but are necessary to protect public health and safety.
4. **Alliance**	Current NRC and Agreement State programs continue, but work to develop national regulatory priorities and products in a collaborative manner. Decisions are based on group consensus. Agreement States assume greater responsibility for decisions and for devoting resources to develop regulatory products.
5. **Delegated Program**	State Agreements as they exist today would cease. NRC develops rules and maintains authority over all licensing and inspection functions. NRC may authorize states to implement the licensing and inspection portion of the program under contract to NRC. Authority is delegated to the state for the term of the contract or agreement.
6. **Single Regulatory Agency**	Regulatory authority over radioactive materials nationwide is the responsibility of a single federal entity. This entity could be NRC, the Environmental Protection Agency, the Food and Drug Administration, or some new entity responsible for regulating all radioactive material.

Options for a National Materials Program

The Working Group considered the current regulatory program structure and a range of other options.

The Working Group included the current regulatory program in evaluating options for a National Materials Program as a base case. The Working Group also considered extremes to bound its assessment. For example, "Independent States" eliminates NRC oversight and most of its involvement in materials regulation. Conversely, "Single Regulatory Agency" eliminates state authority for radioactive materials regulation.

Comparison of Options Table

	Current Program (Base Case)	Independent States	Minimum NRC Involvement	Alliance	Delegated Program	Single Regulatory Agency
Change in AEA required	No	Yes (Agreements)	No	Yes (NARM)	Yes (Agreements and NARM)	Yes (Agreements and NARM)
Agreement States	Yes	No	Yes	Yes	No	No
# of Agreement States Assumed	32	0	32	32/50	0	0
NRC jurisdiction over federal facilities	Yes	Yes	Yes	Yes	Yes	Yes
No. of state programs possible	32	50	32	32/50	0	0
No. of states where NRC has jurisdiction	18	0	18	18/0	50	50
NRC licensing	Yes	Yes	Yes	Yes	Yes	Yes
NRC physical inspection	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Guidance development	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Rule development	Yes	Yes	Yes	Yes	Yes	Yes
Evaluation of state regulatory programs	Yes	No	Yes	Yes	Yes	Yes
IMPEP	Yes	No	No	Yes	No	No
Estimated NRC resources in millions and (FTE)	$55(336)	$3.7(23)	min. support $36.7(269) min. program $32.0(200)	32 states - $51.6(315)/ 50 states - $24.7(135)	$76(368)	$113(744)

Comparison of Options

The Working Group compared and contrasted various attributes of the six options detailed in this report.

In contrast to the Current Program, the NRC would probably not support a national radioactive materials program in the **Minimum NRC Involvement Option**. This option considered NRC regulating only AEA material and continuing a voluntary Agreement State program with 32 states. Under this scenario, NRC would retain approximately five thousand licensees, would resemble a very large Agreement State and would maintain only minimum oversight of the Agreement States. In the **Minimum NRC Involvement Option**, NRC would be involved in inspections and guidance development to a limited degree. Because the AEA does not require the review of Agreement States to be as comprehensive as the current IMPEP, NRC would discontinue its use of the IMPEP. The Working Group recognizes the limitations of this option, but it was included to illustrate the impact of policy decisions on resources.

In contrast to the above option, the **Alliance Option** reflects an evolution of the Current Program and offers many enhancements to the current regulatory programs of both NRC and the Agreement States. The **Alliance Option** includes the collaborative development of regulatory products (rules and guidance) to enhance the development of a consistent national program. Agreement States, industry and other stakeholders could participate more fully by jointly setting national priorities and agendas. More resources and people would be shared among all agencies to accomplish the common goals, as defined by the national priorities and agenda, while protecting public health and safety and providing the maximum flexibility when meeting those national goals and priorities. Although IMPEP would be retained in the Alliance, it is possible that it may be changed to reflect new performance indicators required under a National Materials Program.

The three remaining options considered would require changes to the AEA if they were to be implemented. In the **Independent States Option**, a change in the AEA would abolish NRC's materials program for non-federal entities. NRC would not conduct any state oversight. Some states would need to modify their legislation to assume authority over AEA material and may need to adopt a radioactive materials program similar to the program conducted by Agreement States today. Some states may not choose to support a radioactive materials program, and this would create a regulatory gap for AEA materials nationally. The Working Group included this as an extreme to bound the options, though the group determined that it does not meet the mandatory goal of protecting public health and safety. It is possible that states would maintain a voluntary version of the IMPEP. However, without national performance standards, or a mechanism for assuring compliance, the Working Group believes that the IMPEP program would survive only as a set of voluntary guidelines.

Comparison of Options - cont'd

The Working Group compared and contrasted various attributes of the six options detailed in this report.

Another option requiring a change to the AEA would be the **Delegated Program**. This program would abolish the Agreement States program, leaving the entire regulatory program to be run by NRC. This program is envisioned to be similar to the current FDA delegated programs for mammography. Input from stakeholders at the meeting in Arlington, Texas revealed many problems associated with the operation of a delegated program. While many problems can be overcome, the effort to abolish the current program and reconstitute a delegated program across 50 states would be very challenging from cost, organizational and political perspectives. Considerable effort would be expended to change the AEA, abrogate existing agreements, set up a delegated program, negotiate the terms of a delegated program with each state, and to set up a policing function to assure consistency across the delegations. It is possible that a modified form of IMPEP could be retained; however, the Working Group observes that this process would probably be prescriptive and not performance based. In the Working Group's analysis, this option would consume resources at a rate almost equal to that of the Single Regulatory Agency Option.

The third option requiring a change to the AEA is the **Single Regulatory Agency** for AEA material. This would be a reversion to the regulatory program for AEA material of the early 1960's. A change in the AEA would abolish the Agreement State Program and NRC would resume regulation of all byproduct material. A modified IMPEP could be continued on a regional basis; however, the number of regions cannot be estimated. Conceivably, there could be one region for each state (50), or at least a region in larger states and some consolidation of groups of smaller states. When considering this option, the Commission would need to account for reconstituting a large training program to prepare the number of staff necessary to administer such a large centralized program. In general, changes to statutes (of either NRC or Agreement States), costs, time, effort, and effect to the AEA would need to be considered.

Under the **Single Regulatory Agency Option**, NRC resources are projected to increase to absorb work currently conducted under Agreement State programs. This option is inconsistent with the present trend where the federal government is transferring responsibility for all, or parts, of its programs to the states. It also appears to provide the least degree of public confidence as it seeks little input from affected stakeholders and would not accommodate state views.

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The following portions of this Section describe each option in more detail.

Current Program

NRC and 32 Agreement States regulate AEA materials. NRC has leadership responsibility for AEA material and certain oversight functions over Agreement States. The 32 Agreement States and the 18 non-Agreement States have jurisdiction over NARM.

What are the roles/responsibilities of the NRC for each program element?	NRC is responsible for regulation of AEA materials, licensing, inspection, rule promulgation, guidance development, incident/allegation investigation, and Agreement State oversight. NRC also has regulatory responsibility for federal entities, areas of exclusive federal jurisdiction and materials subject to international safeguards.
What are the roles/responsibilities of Agreement States for each program element?	States have authority for regulation of all radioactive material, licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation.
Are statutory changes required?	No.
What coordination is required?	Coordination exists between the NRC and states individually or through the OAS and CRCPD.
What resources are needed (federal and state)? Who would pay?	Each regulator provides workforce and financial resources to perform their respective legislative mandates. On joint projects, the NRC pays per diem and travel and states pay salaries and provide time away from routine work.
Accountability	NRC is accountable to Congress, licensees, and public. Agreement States are accountable to State legislative and executive branches of their respective governments, licensees and the public. Agreement States are subject to NRC oversight.
Program Assessment	Agreement States, NRC Regional Offices, and Headquarters sealed source and device (SS&D) evaluation program are periodically reviewed using the IMPEP process.
Program Gaps	NARM is not regulated uniformly, if at all, in non-Agreement States and at federal facilities.

Current Program

Advantages

The Current Program functions in a semi-consultative/advisory way, with NRC assuming a strong leadership role. Section 274 of the AEA emphasized cooperation between NRC and Agreement States. NRC sets standards, determines compatibility for these standards and evaluated adequacy and compatibility of Agreement State programs. The Current Program has established a high nationwide standard for radiation protection for AEA materials. Agreement States apply these standards to non-AEA materials they regulate.

Disadvantages

No mandate exists in a consultative/advisory relationship for NRC to accept solicited advice, whether it comes from the states, licensees or other stakeholders. The Current Program is not an equal partnership between NRC and Agreement States. Historically, the Current Program has not encouraged NRC to identify and use expertise from states nor has it provided a means for NRC and states to jointly establish a national regulatory agenda.

The Current Program creates duplication of efforts. For example, in Agreement States, licensees that distribute devices to persons who are exempt from licensing must obtain two licenses:

- one from the NRC to distribute devices
- one from the Agreement State to possess radioactive material

Another duplication occurs in writing regulatory guidance. Rules currently are drafted a minimum of three times:

- by NRC
- by CRCPD as a Suggested State Regulation
- by each Agreement State according to its own administrative procedures

Current Program

1. Roles and Responsibilities of NRC and States for Each Program Element

A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

States

Agreement States license byproduct, source and special nuclear material in certain quantities, as well as NARM.

Specific licenses are issued. Mechanisms used in specific licensing are reasonably consistent among the states. However, mechanisms for general licenses and the level of communication and contact with general licensees varies widely among Agreement States.

Most Agreement States also have SS&D evaluation programs that include NARM.

The licensed waste disposal facilities in the United States are located in and regulated by the Agreement States of South Carolina, Washington, and Utah.

NRC

NRC licenses:

- AEA materials in non-Agreement States
- activities at most federal facilities
- distribution of radioactive devices to persons exempt from licensing
- use and possession of special nuclear material greater than certain quantities
- disposal at sea of byproduct, source and special nuclear materials
- import and export of AEA materials

NRC regions evaluate and issue license for byproduct, source and special nuclear materials. NRC issues specific licenses. NRC uses different mechanisms with General Licensees.

NRC conducts SS&D evaluation program and the exempt distribution program from NRC headquarters office.

NRC does not currently regulate a low-level radioactive waste licensee. NRC does maintain a minimal program that supports 10 CFR Part 61 and provides input to the Commission on policy matters.

Current Program

A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning) - cont'd

States

Currently only four Agreement States, Colorado, Texas, Illinois and Washington, have regulatory programs for uranium mining and milling.

Decommissioning licensed facilities in Agreement States is generally an integral part of their licensing and inspection programs.

NRC

NRC licenses and inspects uranium recovery facilities in non-Agreement States. NRC also makes final determination on site closures for uranium recovery facilities in all states.

NRC ensures the decommissioning of licensed facilities in accordance with its rules and guidance for formerly licensed sites, the Site Decommissioning Management Plan (SDMP). Decommissioning licensed facilities is performed by NRC licensing and inspection programs. NRC has recently implemented a grant program to Agreement States. Grants will fund evaluation of the remaining formerly licensed AEC/NRC licensees within a state's jurisdiction.

Current Program

B. Performing Materials Inspections

States

Agreement States inspect facilities located in their jurisdictions using procedures similar to NRC's IMC 2800. States also conduct inspections of licensees working under reciprocity in their jurisdictions. Reciprocity notifications are required. Each state can establish how long a licensee may operate under reciprocal recognition in their state. The duration for reciprocity ranges from 30 to 365 days in a year.

Agreement States use different mechanisms for providing regulatory oversight for general licensees. The type and frequency of inspection of general licensees varies among the existing regulatory programs.

NRC

NRC performs inspections of specific licensees as specified in Inspection Manual Chapter (IMC) 2800. NRC also performs inspections of exempt distribution licensees located in both non-Agreement States and Agreement States.

Reciprocity notifications are required. NRC conducts reciprocity inspections of Agreement States licensees when licensees are working in NRC jurisdictions. NRC may choose to conduct inspections at Agreement States licensee's home office to review activities conducted in areas under NRC jurisdiction. Reciprocity is limited to 180 days in any calendar year.

In FY 2001, NRC implemented rules to register and track certain general licensees using the General License Tracking System.

Current Program

C. Incidents/Allegations

States

Agreement State inspection programs investigate incidents and allegations. As a matter of compatibility, Agreement States are required to report any reportable events to the NRC on a monthly basis. Incidents involving NARM and machine produced radiation may also be reported to NRC to be included in NMED. Incidents involving media attention are also reported.

NRC

NRC's inspection programs investigate incidents and allegations; NRC tracks allegations separately. The Nuclear Materials Event Database (NMED) is used by the NRC to trend and evaluate events involving equipment and licensees. NRC and Agreement State events are tracked and evaluated by the Generic Assessment Panel to identify safety significant events and generic issues. NRC reports annually to Congress on abnormal occurrences on behalf of NRC and Agreement State licensees. NRC uses some event data to demonstrate accomplishments under its Strategic Plan.

Current Program

D. Materials Licensing Guidance, Inspection Guidance and Rulemaking

States

Agreement States develop and share guidance with other states. CRCPD coordinates with states through Working Groups that develop some licensing guidance. Some Agreement States develop guidance for their programs independently or by modifying guidance in the NRC's IMC 2800 or NUREG 1556 series. Some states choose to use the NRC's guidance without modification. States also adopt or use guidance in a manner similar to NRC.

Agreement States provide comments to NRC on its rulemaking agenda and on proposed rules. After NRC has established the compatibility level for a rule and adopted it, Agreement States typically have three years from the effective date of that rule in which to adopt the rule or implement other legally binding requirements.

NRC

NRC develops licensing and inspection guidance for AEA material licenses and requests input from Agreement States. Most licensing guidance is found in the NUREG 1556 series. In developing its guidance, NRC must consider use of existing guidance from standards developing organizations. Guidance from other entities, such as the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), International Atomic Energy Agency (IAEA) or International Standards Organization (ISO), and other professional organizations is also considered when appropriate. NRC responds to documented trends, incidents, inspection findings, petitions, technological advancements and research. NRC establishes the rulemaking agenda, drafts the rule (with Agreement State participation and input for some rules), establishes the compatibility categories for or within each rule, and monitors implementation in keeping with its oversight function.

E. Training, Qualifications and Experience Standards for Regulatory Personnel

States

Agreement States develop and train staff to meet their program requirements. Many states use training programs developed by NRC. When needed training programs are unavailable, states either contract with groups within their state or join with other states to provide specific training for their staffs. The adequacy of each Agreement State's training program is evaluated during IMPEP reviews.

NRC

NRC staff are trained and qualified as specified in IMC 1246. The adequacy of training for regional staff is evaluated during IMPEP reviews.

Current Program

2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC communicates with others by working with organizations and groups and by distributing information. NRC works with OAS and CRCPD. NRC distributes documents such as All Agreement States Letters, enforcement notices, the Regulatory Agenda, and bulletins to convey information.

Agreement State representation in NRC working groups is often solicited through OAS. NRC and OAS Executive Board review the status and progress of joint Working Groups, receiving information monthly from Working Group chairs. NRC provides no direct funding to the OAS, but funds the transcription services provided for the OAS annual meeting.

NRC has worked with CRCPD for many years. NRC provides funding directly to CRCPD thorough a federal umbrella grant administered by the Food and Drug Administration (FDA). NRC provides a liaison to the CRCPD's Board of Directors. The liaison participates in all meetings of the Board and serves as a conduit for the flow of information between NRC and CRCPD. CRCPD's working groups modify NRC rules to adapt for state use. CRCPD Working Groups draft rulemaking, guidance and other documents for non-AEA materials which are usually adopted by the states. The CRCPD's SSRCRs are available for use by states.

Individual Agreement State programs coordinate with NRC on routine regulatory issues. States respond to NRC requests for comment on activities such as rulemaking plans, proposed rules, and guidance documents. Agreement States provide personnel to serve on various NRC working groups. Agreement States provide information on incidents, misadministrations, and other activities that assist NRC in evaluating current trends and in fulfilling its responsibility in reporting to Congress. Agreement States must conduct activities such that NRC finds them adequate to protect public health and safety and compatible with the NRC. States, either independently or in groups, may also draft rules as necessary.

3. Are Statutory Changes Required for this Option?

No statutory changes are needed to maintain the current program.

4. What Coordination is Required?

No additional coordination efforts were identified to maintain the current program.

Current Program

5. Resources Needed and Who Pays?

NRC resources support materials licensing, inspection, guidance development, incident/allegations investigations, research, legal advice, adjudication, enforcement, and IMPEP (travel and per diem for state members). Agreement State resources support materials licensing, inspection, guidance development, incident/allegations investigations, legal advice, adjudication, enforcement, and IMPEP (salary for state members). NRC pays travel and per diem for state members on working groups, advisory committee members, and steering committees. States pay the salary for their staff who serve and allow them the time to perform the duties.

NRC resources are also used to support the NMED and SS&D Registry databases with the information being provided by NRC and the Agreement States. NRC and Agreement State resources also support their respective rulemaking processes, including public meetings and the cost of publishing and distributing rules.

CRCPD uses funds provided by NRC to CRCPD through the FDA umbrella grant to develop SSRCRs and technical support documents. NRC resources for various program functions are shown in Figure 3.1. These numbers will be used to compare relative changes to resources for various options described.

Figure 3.1 - NRC Resources for Current Program

Activity	Costs* $ in millions	FTE
NMSS**, Regions	$ 26.6	197
Direct Support***	$ 10.0	63
Agency Overhead****	$ 18.4	76
Total	$ 55.0	336

* These resource estimates are based on NRC's FY 2001 budget, and used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.

** NMSS means NRC's Office of Nuclear Materials Safety and Safeguards.

*** These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

**** These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

Current Program

6. Accountability

NRC is accountable to Congress for all activities under the AEA. States are accountable to their respective legislative and executive branches of government. State accountability involves activities within state jurisdictions regarding state radiation control statutes and rules. All regulatory agencies are accountable to their licensees and members of the public. Agreement States are required to report certain information to NRC as a matter of compatibility.

7. Program Assessment

NRC is responsible for evaluating Agreement State radiation control programs and NRC Regional materials programs. NRC uses an integrated method using common and non-common performance indicators as specified in Management Directive 5.6, Integrated Materials Performance Evaluation Program (IMPEP). NRC's Office of State and Tribal Programs has the leadership responsibility for coordinating Agreement State IMPEP reviews; NRC's Office of Nuclear Materials Safety and Safeguards coordinates NRC regional materials program IMPEP reviews. NRC and Agreement State members are trained to conduct IMPEP reviews. NRC schedules the reviews, assigns the review team members and manages the entire process. Review teams are comprised of three or more members, one of whom is from an Agreement State. A team, comprised of three Agreement State staff and one NRC staff member, was used for the review of Headquarter's SS&D program. The IMPEP review of states evaluates the adequacy and compatibility of the state's programs. NRC uses its IMPEP process to review regional materials programs for adequacy.

8. Program Gaps

The AEA does not address NARM. NARM licensees of the NRC located in non-Agreement States and federal facilities are subjected to widely varying regulatory practices. Some non-Agreement States have aggressive licensing or registration programs for these non-AEA materials, while other states have no programs. Federal facilities and Indian tribes located in either Agreement or non-Agreement States can use non-AEA materials without regulatory oversight. For example, an employee of a federal agency (in the performance of official duties) can use a portable device containing NARM without regulatory oversight in any state.

Independent States

Independent States assume responsibility for AEA materials in their jurisdictions. Section 274 of the AEA, which includes the Agreement State program, is abolished. No NRC oversight of state programs exists. NRC relinquishes control of AEA materials to the states and maintains authority over federal facilities and certain quantities of special nuclear material. The resulting national program could be either separate independent groups of states that function as one unit but separate from NRC, or fully autonomous states operating independently from one another.

This option does not include a mechanism that ensures uniform protection of public health and safety on a national level, but it is included as an extreme to help bound the remaining options.

What are the roles/responsibilities of NRC for each program element?	NRC is responsible for regulation of AEA materials, licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation only at federal facilities and in areas of exclusive federal jurisdiction. NRC continues to have authority over materials subject to international safeguards. NRC is not responsible for state oversight.
What are the roles/responsibilities of an Agreement State for each program element?	States have authority for regulation of all radioactive material, including licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation functions.
Are statutory changes required?	Changes to the AEA are needed to disassociate NRC from some AEA materials responsibilities. The Agreement State program ceases and states may need to obtain statutory authority to regulate AEA materials.
What coordination is required?	In its purest form, this option would involve no coordination. In practice, states may decide to coordinate through an entity such as OAS or CRCPD.
What resources are needed (federal and state)? Who would pay?	Each entity would fund its own program as necessary to meet its own needs.
Accountability	NRC and states are accountable to the same entities described in the Current Program.
Program assessment	Federal and state regulatory programs would be self-assessing. No federal oversight exists and therefore no assessment of the national program occurs.
Program Gaps	Possible gaps when interstate issues are involved for NARM and AEA materials.

Independent States

Advantages

Independent States option saves some NRC resources because NRC would be relieved of its responsibilities for regulating AEA materials in the states.

States gain complete control over all uses of radioactive materials within their borders, allowing them to develop a homogenous program.

States develop regulatory products and tailor their programs to fit their own needs and have ultimate flexibility.

Regulatory requirements for all radioactive materials are consistent within each state if coordination occurs.

Disadvantages

NRC retains all of the elements of a materials program because it continues to regulate federal facilities and certain quantities of special nuclear material. However, the scope of NRC's materials program changes because of the different mix of types of licenses and the smaller licensee base. There may be an erosion of expertise within NRC.

Not all states would be willing or able to accept responsibility for regulating AEA materials. Statutory or financial barriers could prevent establishing a more comprehensive program. In addition, a small number of AEA materials licensees in a particular state would also make it impractical to implement a program. As a result, AEA materials may go unregulated in some states.

Lack of compatibility or consistency between state programs could adversely affect licensees who operate in several states to an even greater extent than it currently does. Licensees would be faced with an even greater degree of inconsistency than at present, resulting in higher costs as they deal with these different and possibly divergent programs. Their ability to maintain a compliant operation would be hampered.

Without interstate coordination between individual state regulatory programs, duplication of effort would be unavoidable as each entity took it upon itself to "reinvent the wheel" to respond to radiation safety challenges of changing and new technologies.

Independent States

1. Roles and Responsibilities of NRC and States for Each Program Element

Under this Option, states have the responsibility for addressing radiation protection program elements. NRC has the responsibility for addressing radiation protection program elements only at federal facilities and in areas of exclusive federal jurisdiction. NRC continues to have authority over materials subject to international safeguards.

2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC discontinues its regulatory authority over AEA material in all states, as it does now in Agreement States. In addition, NRC relinquishes its oversight role for adequacy and compatibility of state regulatory programs. However, in several areas NRC may need to retain control:

a. radioactive material at federal entities, such as VA hospitals and government departments
b. radioactive material in areas of exclusive federal jurisdiction, such as tribal lands
c. radioactive material subject to international safeguards such as special nuclear materials in quantities sufficient to form a critical mass and certain other materials, which are the subject of nuclear non-proliferation treaties. Note that the federal government has international treaty obligations related to safeguards of these materials and it is unlikely that these obligations can be transferred to a state.

NRC is responsible for licensing including SS&D evaluations, compliance inspections, investigations, enforcement and development of rulemaking and guidance only to the extent necessary for regulation of materials specified in (a), (b) and (c).

To the extent that each state is willing or able to accept the responsibility, NRC transfers control to each state for all AEA material not covered in (a), (b) and (c) above. Each participating state would be responsible for licensing, compliance inspections, investigations, enforcement, and developing rules and guides. States would also continue to be responsible for low-level waste facilities within their borders.

3. Are Statutory Changes Required for this Option?

Changes to the AEA would be required. Revision to relieve NRC of the responsibility for regulating AEA material in all states, and for the oversight of state programs, currently required by Section 274, would be necessary.

For each state to accept this responsibility, state legislation may be needed in order to incorporate AEA materials into their program. Programs may also need to be restructured to accommodate the change.

Independent States

4. What Coordination is Required?

With one or more independent groups of states operating autonomously, a coordinated national effort to harmonize programs would be needed. However, unless all states participated in this coordinated effort, problems of inconsistency and duplication would exist. A redesigned CRCPD could provide the basis for nationwide coordinated effort. On the other hand, if 50 separate states operated their programs autonomously, no coordination would be required.

5. Resources Needed and Who Pays?

Each entity would fully fund its own program as necessary, either from license fees, general revenue funds, or combinations of sources. Figure 3.2 compares NRC resources currently expended on various program elements and the resulting change to program costs under this Independent States option.

Figure 3. 2 NRC Resources for Current Program and Independent States Option

Activity	Current Costs* ($ in millions)	Current FTE	Independent States Costs ($ in millions)	Independent States FTE
NMSS, Regions	$ 26.6	197	$ 2.0	14
Direct Support**	$ 10.0	63	$ 0.4	4
Agency Overhead***	$ 18.4	76	$ 1.3	5
Total	$ 55.0	336	$ 3.7	23

Source: NRC's FY 2001 budget

* Costs are the sum of contract support, travel costs and staff salaries and benefits .

** Resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

*** Resources include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

Independent States

NRC continues to be responsible for approximately 500 materials licenses held by federal government departments and in the areas of exclusive federal jurisdiction. This represents approximately 10% of the number of licenses currently under the NRC's control, and because of this, the number of NRC FTE required would decrease. When the reduction would result in less than one FTE, the working group assigned one FTE so that a presence would be maintained. Because NRC's oversight of state programs would no longer be required, and virtually all AEA materials licenses would be turned over to the states, many program elements currently residing at NRC, such as the Office of State and Tribal Programs and NMSS support of state activities would disappear completely. Additional resource decreases are found in the areas of research, licensing, inspection, and writing guidance.

6. Accountability

NRC and states are accountable to the same entities described in the Current Program.

7. Program Assessment

Section 274 of the AEA would be abolished, along with NRC's oversight authority. NRC would not have oversight responsibility and without a lead federal entity, there would be no formal regulatory program review. However, states might find it beneficial to know the abilities and scope of other state programs. For instance, how out-of-state licenses or SS&D evaluations are accepted from other states would be of interest. In such cases, CRCPD might implement some form of voluntary program review. CRCPD has such a role in Licensing State designations.

8. Program Gaps

Significant gaps in radiation protection programs could occur. Seriousness would depend on the degree to which states choose to undertake responsibility for regulating either NARM, AEA material, or both. States may choose to:

- regulate neither AEA material nor NARM
- register NARM
- license NARM
- register (former) AEA material
- license (former) AEA material
- use any combination of the above to regulate the use of radioactive material

In addition to gaps in individual programs, additional gaps due to the lack of formal coordination between state programs could occur. For example, gaps could develop when interstate issues such as reciprocity are involved.

Minimum NRC Involvement

Minimum NRC Involvement requires NRC to maintain authority over AEA materials. NRC maintains a voluntary Agreement State program. NRC streamlines its operations to continue to meet the minimum requirements of the AEA. NRC can determine the intensity and level of its activity. Depending on how NRC modifies its policies to meet the minimum requirements of an adequate program, cost savings may occur. NRC maintains authority at federal facilities, in non-Agreement States, and over AEA material in Guam, Puerto Rico, U.S. Virgin Islands, and the District of Columbia (unless those entities desired to become an Agreement "State" as provided by Section 274(n)).

Uniform core regulatory requirements would exist in the United States to ensure a consistent approach to regulating the use of AEA material, especially in "basic radiation protection standards and definitions." Promulgation of new rules or modification of existing rules in 10 CFR Parts 19, 30-40, 61, 71, and 150 would either not occur, or occur only when there is a significant need for modification.

Other regulatory activities such as guidance development and research can be modified to allow NRC to meet its minimum legislative requirements. These other activities were not evaluated by the Working Group for their health and safety significance, but could serve as examples for later consideration.

What are the roles/responsibilities of NRC for each program element?	Most program elements common to NRC and states are not specified in the AEA, but exist as policy decisions to execute NRC's charge for maintaining health and safety. NRC modifies its current policies and requires less resources to implement the AEA. **The role of NRC in each program element changes due to policy changes**. The number of NRC licensees and the number of Agreement States continues to change.
What are the roles/responsibilities of Agreement States for each program element?	Agreement States have responsibility for all elements within their jurisdiction.
Are statutory changes required?	No. This Option assumes the current AEA status, with some NRC policy changes.
What coordination is required?	NRC's OSTP eventually has a larger number of Agreement States to work with, but the basic program structure already exists. Better coordination among Agreement States and with NRC results in better use of resources.
What resources are needed (federal and state)? Who would pay?	Federal resource requirements decrease, but resources continue to be necessary to carry out activities specified in the AEA. NRC needs appropriated funding because of smaller licensee fee base. States continue to fund their own programs.
Accountability	Accountability does not change from the Current Program.
Program assessment	Program assessments can be significantly reduced to match NRC's reduction in resources. IMPEP may be reduced to a telephone call or self-evaluation.
Program Gaps	Program gaps are the same as those identified in the Current Program. Experience and expertise may continue to shift away from NRC with the declining licensee base.

Minimum NRC Involvement

Advantages

NRC and Agreement States would save resources. NRC probably would decrease rulemaking which decreases corresponding state efforts.

Disadvantages

NRC must develop less resource-intensive methods to assure that public health and safety is maintained.

If NRC reduced or eliminated IMPEP and NMED, there might not be a centralized source of information for NRC to assess the efficacy of the national program.

Some licensees will continue to be subject to more than one regulatory agency, and licensees with interstate activities will continue to deal with multiple jurisdictions and rules.

Minimum NRC involvement reduces coordination between NRC and States.

Minimum NRC Involvement

1. Roles and Responsibilities of NRC and States for Each Program Element

A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

States

Minimal changes would be required in Agreement State programs. If NRC issues more types of general licenses, states would be requested by industry to do the same. If exempt distribution could be authorized by Agreement States, minimal effects to Agreement States and savings for licensees could result.

Agreement States that perform safety evaluations would continue to do so. States that have agreed to let NRC do such evaluations may need to develop an evaluation program.

States would be responsible for addressing all new issues developing in the waste arena.

There would be no change to uranium recovery or decommissioning programs.

NRC

NRC could modify how it licenses AEA material. For example, the number and frequency of licenses reviewed and issued could be decreased by expanding general licensing and/or establishing a registration program.

The *a priori* safety evaluation of SS&Ds containing AEA material is not specified in the AEA, therefore, NRC could evaluate each device every time a licensee wishes authorization to use such a device. However, this is not an efficient mechanism for licensing. NRC continuing to issue SS&D evaluations would be the best alternative. On the other hand, the requirement for NRC to maintain a SS&D registry is not specified in the AEA. This task could be eliminated, contracted, or published on a website, with each regulatory agency voluntarily posting information.

The Low-Level Radioactive Waste Policy Amendments Act of 1985 gave states responsibility to dispose of low-level waste generated within their borders. It allows states to form Compacts to locate facilities to serve a group of States. Staff in the reactor arena could assist with some low-level waste issues.

There would be no change to the current uranium recovery and decommissioning programs.

Minimum NRC Involvement

B. Performing Materials Inspections

States

There would be no change required in the Agreement State programs.

NRC

Inspection of licensees is not specified in the AEA; however, the Working Group has identified an inspection program to be a necessary component of an adequate program. The scope of NRC's inspection program is policy driven; therefore, NRC could modify its method of performing inspections by contracting inspections, or by allowing self-inspections by licensees, with NRC retaining the final determination of public health and safety. In addition, NRC could modify the scope and frequency of inspection of licensees, including reciprocity inspections in the non-Agreement States, territories, and the District of Columbia.

C. Incidents/Allegations

States

No change would be required in the Agreement State incident response programs. Agreement States would no longer be required to report to NRC if NMED is eliminated, or would be required to report only the most egregious incidents to a scaled-back NMED.

NRC

NRC response would be limited to licensees under NRC jurisdiction. The NMED system, used for generic assessment and event tracking, is not required under the AEA, and could be limited to NRC-licensee events. Under the most far reaching changes to NRC's program, NMED could be deleted.

Minimum NRC Involvement

D. Materials Licensing Guidance, Inspection Guidance and Rulemaking

States

As NRC generates fewer changes to rules, state rulemaking will decrease and fewer compatibility issues will result. Agreement States would continue to develop individualized rules, but would continue to be required to be compatible with NRC's basic radiation protection standards.

Agreement States would use sources of information from CRCPD's SSRCRs, standard developing organizations, and other federal and state agencies.

NRC

NRC would need rulemaking resources for basic radiation protection standards and amending 10 CFR Parts 19, 30 through 40, 61,71 and 150. NRC would rely heavily on other entities for developing standards and rules; NRC would follow the Administrative Procedures Act for final adoption of rules.

NRC's activity in developing or maintaining guidance documents could range from non-existent to limited, for instance, to developing some basic documents related to radiation safety.

E. Training, Qualifications and Experience Standards for Regulatory Personnel

States

Each state is responsible for maintaining a level of staffing that is adequate to provide public health and safety. Therefore, each state must make sure that staff have adequate training. This option would affect those states that use NRC's current training program because NRC would reduce training opportunities.

NRC

Depending on the assumptions made, NRC's staffing could change dramatically. Increasing the use of general licensing and performing fewer inspections would decrease the number of staff requiring training and qualifying in accordance with NRC's IMC 1246. NRC's Technical Training program would be significantly decreased for the materials arena.

Minimum NRC Involvement

2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC responsibilities continue under the current AEA in:

- standard setting
- oversight of Agreement State programs for adequacy and compatibility
- regulation of licensees in non-Agreement States
- regulation of Federal agencies, areas of exclusive federal jurisdiction, tribal lands
- production and utilization facilities, special nuclear materials (above certain amount)
- disposal in the ocean
- high level waste disposal
- off-shore waters
- certain aspects of mill tailings

This option would require NRC to make dramatic policy changes for executing its obligations. For instance, the AEA requires that NRC take the leadership role in regulation of AEA material throughout the U.S., but it does not define the level of effort required of NRC to meet that statutory obligation. NRC's focus on regulatory research would be in support of the basic radiation safety standards contained in 10 CFR Part 20. Therefore, NRC resource requirements for materials programs would decrease significantly because basic radiation safety would be addressed in the reactor safety arena, with assistance from the materials arena when needed.

This Option requires the NRC to fulfill its obligations under the AEA, but would also include program elements identified by the Working Group as being necessary for an adequate radiation protection program. The Working Group considered more radical changes that were determined not to be protective of public health and safety. For this reason, these were not pursued further.

3. Are Statutory Changes Required for this Option?

This Option assumes no changes to statutory requirements are necessary for NRC, or for the states.

Without change to the AEA, NRC would establish a minimum level of resources necessary to perform its duties, regardless of the number of licensees or the number of Agreement States. With changes in certain policy decisions, NRC could minimize its current level of effort. This could include elimination of NMED and IMPEP.

Minimum NRC Involvement

4. What Coordination is Required?

With the potential minimization of the NRC's program, more collaborative interactions among the states would be required. NRC may continue to need to gather information from all states for unusual events and abnormal occurrences, depending upon policy changes made. Coordinated training would be necessary because the expertise will be shifting from NRC to the states for many categories of licensees.

5. Resources Needed and Who Pays?

The overall effect is minimal for states, but could result in savings for the NRC because fewer NRC resources would be required to support this program. As indicated earlier in this document, the Working Group used the current program as the base case. Compared to the current program, NRC could reduce its resource needs by changing regulatory policy, thus varying the scope of activities, rather than changing statutes. A "minimum" NRC presence could include a wide range of options, depending on the degree to which NRC policy might change.

Because it is impossible to predict what level of regulatory oversight NRC would adopt by policy under a given minimum program, the Working Group evaluated a range of options. Two variations are presented in Figure 3.3 below.

Minimum NRC Involvement

Figure 3.3 - NRC Resources for Current Program and Minimum NRC Involvement

Activity	Current Program Costs* ($ in millions) (FTE)	Minimum Support Option+ ($ in millions) (FTE)	Minimum NRC Program Option++ ($ in millions) (FTE)
NMSS, Regions	$ 26.6 (197)	$ 16.7 (158)	$ 15.0 (105)
Direct Support**	$ 10.0 (63)	$ 5.3 (50)	$ 6.0 (50)
Agency Overhead***	$ 18.4 (76)	$ 14.7 (61)	$ 11.0 (45)
Total	$ 55.0 (336)	$ 36.7 (269)	$ 32.0 (200)

* These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.

** These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

*** These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

\+ This option assumes the NRC licensing and inspection programs do not change, but rule and guidance development are reduced substantially, the general license program is assumed to support follow up for a second round of registrations, NMED and event evaluation support only NRC's licensees, the orphan source and low level radioactive waste programs are eliminated and state program activities are limited to interactions with perspective Agreement States, review of Agreement States and reduced interactions with OAS and CRCPD.

++ This option assumes no materials research, guidance development, IMPEP, orphan source program, or grants for terminated sites in Agreement States; no NMED and no onsite inspections other than in response to incidents. In addition, rulemaking and support to Agreement States are reduced.

6. Accountability

NRC and states are accountable to the same entities described in the Current Program.

Minimum NRC Involvement

7. Program Assessment

The AEA requires NRC to evaluate the adequacy and compatibility of Agreement State programs but the AEA does not specify the depth or scope of reviews. This program effort could be minimized through the modification or elimination of the current Agreement State oversight program, including IMPEP. For example, during the initial years of the Agreement State program, evaluations consisted of only a short visit from a regional NRC representative. Agreement State reviews could be reduced to a visit from an NRC representative, a telephone call update, or the state could be requested to complete a questionnaire for NRC to review and maintain on file.

This Option would require no change to existing agreements between NRC and the States.

8. Program Gaps

Similar to the current structure, non-AEA material at facilities, territories, and states not entering into Agreements is not addressed by this option.

Alliance

An Alliance is a cooperative process between the States and NRC that identifies radiation safety regulatory priorities and the means to address those priorities. The process may operate between the States and NRC or it may involve other federal and state regulatory agencies on radiation issues.

The Alliance Option is the structure that most completely encompasses the common attributes of shared goals and decision-making, shared resources, and shared responsibility.

The Alliance requires a consensus structure, one based on general agreement and consists of decisions/judgements arrived at by most of those concerned. Consensus does not indicate unanimity of a group, but is a process that provides an opportunity for all parties in the group to bring their individual ideas, opinions, and input to the table so that participants are empowered and can agree to accept decisions made by the group.

What are the roles/responsibilities of the NRC for each program element?	NRC and states share responsibility for - identification of regulatory products - prioritization of product development - development of corresponding rules and guidance. NRC would obtain authority for discrete NARM.
What are the roles/responsibilities of Agreement States for each program element?	NRC and states share responsibility for - identification of regulatory products - prioritization of product development - development of corresponding rules and guidance.
Are statutory changes required?	Yes, to eliminate the regulatory gap for NARM.
What coordination is required?	More efficient coordination between the NRC, states, OAS and CRCPD is required.
What resources are needed (federal and state)? Who would pay?	Each regulator provides the workforce and financial resources to carry out their respective legislative mandates. On joint projects, NRC pays for per diem and travel and states pay salaries and provide time to work on Alliance activities. NRC also covers most of infrastructure, e.g., publications, national databases, etc.
Accountability	No change from the Current Program.
Program assessment	Program assessment through IMPEP, including review of states, Regions and NRC Headquarters for SS&D review.
Program Gaps	AEA would need to be amended to include NARM. The only gap regarding radioactive materials would be diffuse NORM.

NOTE CONCERNING RESOURCES: For states, out-of-state travel is more than just a budgetary issue. Often because of policy/political issues, unless funded by someone other than the state, state employees are not allowed to travel out-of-state.

Alliance

Advantages

The Alliance option most completely encompasses the common attributes desired in a National Materials Program. Attributes consist of shared goals and decision-making, shared resources, and shared responsibility.

Advantages to a consensus structure are that all parties have an opportunity, if not an obligation, to participate meaningfully in a spirit of true partnership.

Benefits of consistency in the program result, demands on resources are spread among the participants, and sharing of responsibility occurs. These accomplishments inspire public confidence.

Obvious resource savings accrue when resources are shared.

Disadvantages

Negotiations to achieve consensus require time and resources. Sometimes these costs could be significant. Individuals who participate would need the authority to make the decisions necessary to reach consensus. This may not always be the case.

This option assumes NRC would obtain authority to regulate discrete NARM. This could result in some non-Agreement State radioactive materials programs being dissolved, unless the option encouraged or forced non-Agreement States to seek Agreement State status.

Alliance

1. Roles and Responsibilities of NRC and States for Each Program Element

A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

These activities would be performed as they are in the Current Program. Contracted entities or Centers of Expertise could be used to perform some license reviews or portions of reviews for specific technical areas.

B. Performing Materials Inspections

The current inspection program would be maintained, but would be supplemented with other options. NRC would perform inspections for all facilities authorized to possess and use radioactive materials (now including NARM) in non-Agreement States and at federal facilities in Agreement States. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-Agreement States and Agreement States.

Other options include:

1. allowing other entities to contract with NRC and Agreement States to perform inspections and report results to the appropriate regulatory agency;

2. allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC and Agreement States or reduce inspection effort by NRC and Agreement States*;

3. accept audits performed by other organizations and use these as a supplement to NRC and Agreement State inspections to reduce inspection effort by NRC and Agreement States*; or

4. use Centers of Excellence to perform inspections of specific technical areas.

*Acceptance of licensee audits or audits performed by independent organizations to modify NRC and Agreement State inspection effort would be determined by the appropriate regulatory agency in a selective manner. Centers of Expertise could be either Agreement State or NRC organizations and would be jointly recognized by NRC and Agreement States.

C. Incidents/Allegations

A national Information Infrastructure regarding incidents will need to be maintained.

Alliance

D. Materials Licensing Guidance, Inspection Guidance and Rulemaking

Development of rules and guidance is discussed in detail in "Regulatory Process Under the Alliance" later in this section.

E. Training, Qualifications and Experience Standards for Regulatory Personnel

The current training, qualifications, and experience standards would be maintained and be enhanced with:

1. use of an Information Infrastructure for training ideas, resources, and opportunities designed for or employed by NRC and Agreement States
2. allowing licensees to provide training, on a voluntary basis, for specific technical issues or consider contracting with licensees to train staff in specific technical areas
3. encouraging a regulatory agency exchange program to develop staff in specific technical areas

2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC and States share responsibilities except where noted. NRC maintains oversight for adequacy. NRC funds and continues to coordinate and participate in the IMPEP process. Equal participation under the IMPEP process, with voting status on the management review board for States, should be considered.

The roles and responsibilities of the CRCPD and OAS can vary under the Alliance, depending upon decisions made by the Commission regarding a National Materials Program.

3. Are Statutory Changes Required for this Option?

Congress would need to make statutory changes to authorize NRC authority for NARM. A few Agreement States may have to amend laws so that they may adopt Alliance products. Some laws currently require states to adopt SSRCRs developed by CRCPD.

Alliance

4. What Coordination is Required?

Activities of CRCPD that could be impacted by the Alliance are development of the SSRCRs and the products developed by many of the Environmental Council Committees. In anticipation of potential changes, the CRCPD Board created a committee to evaluate the CRCPD's role in radioactive materials rulemaking and make recommendations to the Board concerning changes in that role. This committee is coordinating its efforts with the National Materials Program Working Group.

OAS activities involving assignment of persons to NRC working groups could be similarly impacted. OAS issues could potentially be addressed through the Alliance process.

Both organizations are involved with the Working Group and are aware of the potential need to evaluate and change the functions of the organizations. Any changes made will be dependent upon the Commission's decision regarding a National Materials Program. If that decision incorporates the Alliance, changes in the organizations will be geared toward reducing duplicate efforts and increasing efficient use of resources.

5. Resources Needed and Who Pays?

Sharing responsibilities with the states would reduce costs to the NRC. While NRC would be required to issue rules, developing them in collaboration with the states will reduce NRC costs. For areas not involving the "core" concerns of the NRC, NRC may not need to be involved in a rulemaking at all, or be involved at a minimum level of effort. The NRC could then choose to adopt the rule through its normal rulemaking process.

Priorities set by decision-makers for the NRC and states are set by those who can commit resources. Resources committed by the states are expected to be the same type of resources currently committed. For example, when a state representative participates on a working group or an IMPEP team, the state pays the position costs and NRC pays the travel and per diem. Because many states have difficulty is funding out-or-state travel, it is preferable that NRC continue to cover travel and per diem. With proper planning and use of conference calls, the majority of the expense for developing a regulation or guidance document would fall to the states that had the leadership role.

Both licensees and taxpayers would pay for the cost of a National Materials Program. The mix between the two will depend on the legislature controlling each agency's budget. It is not expected that all agencies will be equally involved in all areas. On priorities that are high, several agencies will participate, thus spreading the cost. An agency may work on a product independently, either because it chooses to, it is required to by legislation, or as a result of a petition that is not related to a national priority. In that case, the agency, and its licensees and its taxpayers, will cover the entire cost of the work.

Alliance

NRC will regulate NARM. This should not result in a significant increase in resources for the NRC in most categories of licenses. The vast majority of non-Agreement State NORM licensees are already licensed by the NRC because of the AEA materials they use. Regulatory burden for those licensees that are now licensed by both NRC and the non-Agreement States would be reduced. NRC currently devotes resources to NARM. For instance, NRC investigated Mallinckrodt overexposures from NARM. NRC has been involved in issues concerning pre-1978 mill tailings.

Budgeting would be similar to the Current Program. Each regulatory agency would continue to be responsible for the budget necessary to carry out its licensing and inspection activities.

Likewise, each agency would be responsible for directions imposed on it by its legislature and for responding to petitions for rulemaking. Activities conducted jointly among agencies through the Alliance as national priorities are those that the other agencies would have supported independently.

Funding for the Alliance Administrative Core should be evaluated by an implementation committee after CRCPD, NRC, and OAS agree to a formal working relationship with formal communication channels. The functions of the Administrative Core (discussed in detail later in this section) are currently being performed and funded, sometimes in duplication, among states, NRC, CRCPD, and OAS. Some roles will be increased and some will decrease. Efficiencies should reduce overall costs.

The following chart shows current costs and the cost of an Alliance option depending upon the number of Agreement States.

Figure 3.4 - NRC Resources for Current Program and Alliance Option

Activity	**Current Program Costs*** ($ in millions) (FTE)	**Alliance (32 States)*** ($ in millions) (FTE)	**Alliance (50 States)**** ($ in millions) (FTE)
NMSS, Regions	$ 26.6 (197)	$ 24.3 (181)	$ 9.4 (58)
Direct Support	$ 10.0 (63)	$ 10.0 (63)	$ 7.9 (46)
Agency Overhead	$ 18.4 (76)	$ 17.3 (71)	$ 7.4 (31)
Total	$ 55.0 (336)	$ 51.6 (315)	$ 24.7 (135)

* These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits .

** These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

*** These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

Alliance

The Alliance requires a greater commitment of resources compared to other options, but the benefits are significant. Measurement of public confidence is difficult, but the Working Group believes this Option promotes harmony among regulators, encourages public participation, utilizes Centers of Expertise, and makes setting national priorities a very open and participatory process. These things build a stronger national program, which can then enhance public perception of efforts to protect workers and public health and safety.

6. Accountability

NRC and states are accountable to the same entities described in the Current Program.

7. Program Assessment

NRC would retain its responsibility to evaluate Agreement State radiation control programs and NRC regional materials programs using IMPEP. Under an Alliance, NRC may consider allowing an Agreement State representative to be a voting member of the Management Review Board.

8. Program Gaps

If the AEA is amended to incorporate discrete NARM, as recommended by the Working Group and stakeholders, the Working Group does not envision any program gaps other than the regulation of diffuse NORM.

Alliance Makeup and Structure

The Alliance consists of three groups: regulatory decision-makers, other stakeholders, and an administrative core.

Regulatory decision-makers are state radiation regulatory program managers and NRC materials program managers. Regulation of sources of radiation is a regulatory function. By statute, federal and state agencies are charged with this regulatory responsibility. Therefore, these agencies are the ultimate decision-makers regarding radiation regulation, are essential to the regulatory process, and are the central component of the Alliance.

It is also hoped that under the Alliance, regulatory decision-makers would include, or seek the input of other federal and state agencies charged with regulating radiation issues. Other agencies could include EPA, DOE, and equivalent state environmental or health agencies depending on where the state radiation control program is organizationally located.

Other stakeholders include licensees, the public, professional organizations, industry organizations, and other federal and state agencies with an interest in radiation issues. The other federal and state agencies are considered stakeholders because at this time, the effort towards establishing a National Materials Program is being driven by NRC and representatives from the state radiation regulatory agencies. Regulatory decisions by federal and state agencies must be informed decisions. To make such decisions, it is necessary to actively seek and consider input from those persons who would be effected. Stakeholders are also essential to the regulatory process and should be considered as such by the Alliance, as they currently are by individual federal and state agencies.

The *administrative core* can be considered the support staff for the Alliance membership and is essential to the logistical process of the Alliance.

The Role of the Regulatory Decision-Makers

The responsibilities of the regulatory decision-makers within the Alliance include:

1. jointly establishing regulatory priorities and agenda
2. identifying Centers of Expertise
3. recognizing current regulatory successes
4. identifying alternate resources
5. defining/making assignments and committing resources
6. evaluating progress on assignments
7. maintaining a "group" to serve as a coordination interface on Alliance issues

Alliance Makeup and Structure

1. Jointly establishing regulatory priorities and agenda

The Alliance structure supports consensus and provides an opportunity for all parties to bring their individual ideas, opinions, and input to the table. This creates an open forum for regulatory decision-makers to disucss issues. Presumably, the regulatory decision-makers are aware of federal or state agency radiation control priorities and resources. In an open forum created by the Alliance, all the decision-makers may become aware of pertinent regulatory issues across the nation concerning ionizing radiation (both AEA designated radioactive materials and NARM). As has been the case, issues involving NARM can be of higher priority to the state programs that have authority to regulate those materials than other issues involving AEA-designated materials. By bringing all issues to the table, regulatory priorities, an agenda for resolving them, and suggested regulatory products can truly represent national priorities rather than priorities limited to those radioactive materials that NRC has the authority to regulate. (Regulatory productssuggested may include rules, licensing, inspection, and technical guidance documents, etc.)

Jointly establishing priorities and an agenda does not prohibit regulatory agencies from addressing other issues that are identified. For example, during the 2000 OAS meeting, a group of states representatives volunteered to work together and have developed guidance on positron emission tomography (PET), although it was not identified as one of the top three priorities during the tabletop exercise.

2. Identifying Centers of Expertise

Using Centers of Expertise to develop regulatory products was identified as an efficient and preferred method during the evaluation of the essential program elements of a National Materials Program. The most up-to-date knowledge and experience involving any one given use of radioactive material does not lie within any one federal or state agency. Since the inception of the Agreement State concept, Agreement State regulatory programs have not only increased in number, but have matured in knowledge and experience with the various uses of radioactive materials. In numerous situations, Agreement States have the most current knowledge and experience because the uses of radioactive material are often concentrated in certain parts of the country. For instance, well-logging and industrial radiography are more unique to the oil-producing states. Regulation of certain radioactive material is located only in Agreement States, as with licensing and inspection of existing waste disposal sites. Agreement States and Non-Agreement States have knowledge, experience, and statutory authority and responsibility that NRC does not have. Therefore, the Centers of Expertise primarily reside at the state level in those situations. The regulatory decision-makers will identify those Centers of Expertise on a nationwide basis for a particular radiation regulatory issue.

Alliance Makeup and Structure

3. Recognizing current regulatory successes

It is rarely of benefit to "reinvent the wheel" that is turning effectively and efficiently. In evaluating the program elements, the Working Group determined that the current method of accomplishing several of the elements was the most effective or was one of several effective options. Individual agencies, federal or state, have developed alternative methods for accomplishing program elements. The Alliance allows identification and recognition of current successes, and ultimately, more efficiently-produced regulatory products.

4. Identifying alternate resources

The Alliance provides an opportunity to create a collection point for alternate resources that can be used by regulatory agencies. It is not necessary for each federal and state regulatory agency to produce a regulatory product from scratch. It is inefficient to operate under the presumption that a regulatory product can only be valid and recognized by regulatory agencies if that product is initiated, reviewed, and produced by a particular regulatory agency. Federal agencies are required to use consensus standards, unless other options are justified. State agencies frequently share regulatory products. Both federal and state regulatory products often reference other rules and guidance documents, and industry standards. This collection of alternate resources should include not only regulatory products and consensus standards, but also professional and industry organizations that can be used in the developing regulatory products.

5. Defining/making assignments and committing resources

Under the Alliance, groups of regulatory staff members would be assigned to develop a regulatory product for a particular issue. Membership on those work groups would be made considering the Centers of Expertise for that particular issue, the availability of staff to participate on the work group and a regulatory agency's statutory jurisdiction to regulate that particular issue. Creating these work groups focuses the pertinent national resources for particular issues. The Alliance establishes work groups and makes assignments. The work groups are also made cognizant of and should use, where appropriate, the current successes and alternate resources identified by the Alliance.

Because assignment of federal and/or state personnel to a work group involves a commitment of resources, those individuals making the assignment must be empowered to commit those resources. For this and other reasons, the primary membership of the Alliance consists of the regulatory decision-makers. Whether the committed resources involve money, staff member time, or both, assignment of such resources is a commitment towards a mutually established national radiation control priority.

Alliance Makeup and Structure

6. Evaluating progress on assignments

   Progress on those priorities must be evaluated to ensure that the mutually agreed upon national radiation control priorities are addressed in a timely and appropriate manner. The regulatory decision-makers in the Alliance have committed the appropriate resources and should evaluate whether the progress is satisfactory or not. For instance, if time lines were established and not met, the regulatory decision-makers would evaluate the reasons why and make appropriate adjustments to ensure the product is developed and the national radiation control priority is met.

7. Maintaining a "group" to serve as a coordination interface on Alliance issues

   Regulatory decision-makers constitute a large group which will require a coordination interface for communicating within the Alliance. The "interface group" will act as a spokesperson for Alliance issues. The regulatory decision-makers as a whole will designate the membership "group," which should include representatives from both states and NRC.

Role of the Administrative Core

The Alliance requires an administrative component of the regulatory core. The administrative component could consist of a few representatives of states and NRC, or could be a separate entity, as employed by the CRCPD or the Health Physics Society. No decisions or actions on technical or policy issues or established priorities may be made by the administrative component of the Alliance; this would negate the consensus nature of the Alliance.

The responsibilities of the administrative core within the Alliance include:

1. Planning, coordination and logistics

   A support staff function is necessary for Alliance members. The support staff functions must include coordinating the logistics of Alliance meetings, whether those meetings are physical or virtual meetings. Meeting locales and reservations must be arranged and notification of the arrangements must be made to the Alliance members. An agenda for the meeting must be created and distributed. The support group could provide facilitation for these meetings.

   Because the primary membership of the Alliance represents multiple organizations, no one organization should represent the Alliance. However, the membership of the Alliance, including stakeholders, need a centralized point of contact for logistical purposes.

Alliance Makeup and Structure

2. Tracking Alliance assignments/products

   Regulatory decision-makers are tasked with identifying priorities and making assignments. Support staff must maintain documentation of those priorities and assignments, including the desired products, the individuals assigned, and any time lines associated with the assignments. The administrative core will need access to this information and be able to report to the regulatory decision-makers who are responsible for evaluating progress.

3. Maintaining Information Infrastructure

   The roles of the regulatory decision-makers include identifying Centers of Expertise and alternative resources and recognizing current successes. The work groups assigned the development of regulatory products should utilize these Centers of Expertise, alternative resources, and current successes. An Information Infrastructure provides a centralized point for collection of this information and any such data collection needs maintenance. Maintenance of the Information Infrastructure is a support staff function and therefore, a role of the administrative core of the Alliance.

Role of the Stakeholders

Federal and state agencies must make informed regulatory decisions, and under the Alliance would still be required to actively seek and consider input from those persons who would be affected. Stakeholder input would be directed to the Alliance for the regulatory products being developed. For example, if the Alliance work product were a rule, comments on the rule would be directed to the work group assigned to the rule. Any comments directed to NRC or an individual state agency should be forwarded to the work group.

The Alliance in no way negates the opportunity for stakeholders to seek information and provide input to the NRC or to any individual state agency. Developing regulatory products under the Alliance allows stakeholders input and access to a larger audience of decision-makers.

Alliance Characteristics and Functions

Although the Alliance is not a structure in itself, it must operate within a framework. It must have operating procedures in order to function. The framework can vary depending upon the commitment or resources by those involved.

Alliance Makeup and Structure

The Alliance can conduct physical or virtual meetings with the decision-makers from all states and the appropriate managers from NRC. The meetings could be held at an established frequency, such as annually. This provides an opportunity for true consensus because everyone comes to the table and has opportunity for input. Not all states are expected to fully participate, as is the case now. Some states may be more active than others.

Instead of having each individual decision-maker present, representatives of the states and NRC could meet. Decision-makers not present would need to agree to having a representative present their input. It would also require the representative to make greater preparation prior to the meeting by soliciting the opinions and feedback from those decision-makers being represented. From an operational standpoint, the Alliance would need to determine a method of designating the representatives. However, representatives will not be able to commit resources on behalf of all Alliance members. Furthermore, caution would need to be exercised to ensure the consensus of the Alliance was represented.

Work groups assigned regulatory products by the regulatory decision-makers could consist of varying combinations of state and NRC staff, depending on the issue and product being developed. The work groups could consist solely of members from interested states, especially for an issue or product over which NRC has no statutory jurisdiction (non-AEA sources of radiation). Or the work group could consist solely of NRC staff for an issue or product over which state staff have no jurisdiction (federal facilities). The work groups could consist solely of Centers of Expertise for a particular technical issue or could have Centers of Expertise and additional resource members.

The administrative core of the Alliance is a support staff function and can operate in varying ways. It can exist within NRC, in which case, those administrative core members would be federal employees, specifically NRC employees. They could be located within Office of State and Tribal Programs because of that program's existing relationship with the Agreement State programs. However, the non-Agreement States are ideally also a part of the Alliance and would need to be considered. The administrative core functions could be managed by a non-regulatory entity and be funded through contractual funds, such as the current relationship between the Health Physics Society and Burke and Associates. The administrative core functions could also be managed through an existing organizational entity such as NRC or CRCPD's Office of Executive Director, with the addition of FTE(s) and monetary support. The NRC & CRCPD already perform these functions in support of a national regulatory program. Regardless of how the administrative core is staffed and where it is located, compatible information technology capabilities will be required in order to fulfill the responsibilities of maintaining the Information Infrastructure and being the central coordination/contact point for the Alliance.

Alliance Makeup and Structure

Regulatory Process under the Alliance

Work for the Alliance will be done on a voluntary basis. While each agency must develop rules and guidance based on its own needs, legislation and political necessities, the Alliance will allow agencies with similar needs to work together cooperatively. When they work together, resources of staff, money and time are saved.

Under the Alliance, certain fundamental principals will apply for the development of rules and guidance.

1. Rules and guidance will be developed in partnership using Centers of Expertise.
   A standing committee made up of Alliance members - both state and NRC will determine compatibility.
2. Not all Centers of Expertise may want to participate.
3. Each agency must still meet its administrative procedures for the adoption of rules.
4. The Commission will maintain its role in ensuring the framework for a National Materials Program through its ultimate adoption of criteria for adequacy and compatibility for rules

The process will be as follows:

1. Alliance meets and establishes priorities.
2. Regulatory change is identified.[1]
3. Define the work product – e.g., regulation or guidance, scope and depth.
4. Identify Centers of Expertise and establish a working group.
5. Set schedule.
5. The working group drafts the rule, statement of consideration and regulatory analysis, and proposes the level of compatibility.
7. The Alliance's Standing Compatibility Committee assigns compatibility category.
8. Peer review – Alliance and interested stakeholders.
9. Working group reviews comments. If major changes to rule are needed, or, if based on comments, the Working Group believes the proposed compatibility should be changed, the process goes back to step 6.

[1] A change may be identified as a national priority, or some states may agree to cooperate on one of their priorities that did not elevate to a national priority.

Alliance Makeup and Structure

10. If there are no major changes to the rule and no changes to compatibility, the draft is distributed to Alliance members, Agreements States and NRC, with a description of changes since the draft was reviewed.
11. Each agency adopts the rule dependent on desire, internal needs, and compatibility, pursuant to its own administrative procedures.[2]

The role of the Alliance will be to:

1. identify priorities (these may be national priorities, or the alliance may facilitate several agencies working together on priorities that are not elevated to a “national priority”
2. define work product, e.g. rule, guidance or procedure
3. establish the scope, depth and time frame for the product development
4. identify resources needed, e.g. stakeholders, “associates”

The Working Group established to develop the rule Suggested Regulation or guidance will:

1. select a chair(s)
2. develop product
3. report progress
4. have the product peer reviewed and evaluate comments
5. submit the product to the Alliance core

The Alliance’s Administrative Core will track and report on the working group’s progress, and when finalized, distribute the product to the Alliance members and the Alliance’s Information Infrastructure.

[2] The Working Group proposes that the current 3-year implementation criteria will be continued under the Alliance.

Delegated Program

NRC or some other federal entity establishes requirements for licensing and inspection of all radioactive material. States would no longer hold Agreements with NRC, but NRC would be able to delegate certain duties to states. Note that this Option allows for delegation of duties, not authority.

What are the roles/responsibilities of the NRC for each program element?	NRC is responsible for developing a National Materials Program to meet all program elements.
What is the role/responsibility of an Agreement State for each program element?	Agreement States would cease to exist. States could contract with NRC to perform some duties from program elements.
Are statutory changes required?	The AEA must be amended to include NARM, delete the Agreement State program, and add provisions to include delegated programs. States may also need to modify their legislation.
What coordination is required?	NRC must coordinate efforts on a national level to ensure no program gaps are created.
What resources are needed (federal and state)? Who would pay?	Licensees would pay, and NRC would provide funding to states according to the terms of each contract.
Accountability	NRC would be accountable to the licensees and the public. States would be accountable to NRC under the terms of their contracts.
Program Assessment	NRC would assess the performance of each state performing delegated duties at the time of contract renewal at a minimum.
Program Gaps	This Option assumes the AEA is amended to include NARM. NRC essentially has responsibility for regulating all radioactive material in the US under this Option, therefore eliminating program gaps.

Delegated Program

Examples of Two Existing Delegated Programs
The Environmental Protection Agency (EPA) currently delegates some of its programs to states. The Food and Drug Administration (FDA) also delegates programs under the Mammography Quality Standards Act (MQSA). The Working Group chose to model the Delegated Program option after the FDA's MQSA program because:
1. many of EPA's delegated programs are split among several different state agencies;
2. MQSA is a radiation protection program and typically resides in the same state agency as the state's x-ray program.

Under MQSA, states can sign contracts with FDA to perform inspections for FDA at facilities performing mammography. These contracts must be reviewed annually. In exchange, states are provided training, equipment (instruments and phantoms), and laptop computers for filing inspection reports. States also receive funds from the FDA for each inspection performed. State personnel inspect facilities against FDA's rules and in accordance with FDA's procedures. Inspection data are provided to FDA. FDA is responsible for enforcement and issuance of certificates for mammography facilities.

The Working Group recognizes that there are many obstacles to implementing this Option; however, it has been presented as a program that has worked for other federal agencies and states. The Delegated Program option could be used to supplement the current Agreement State system and NRC's efforts to verify a consistent approach to regulating radioactive materials. For example, NRC could contract with states to perform inspections at VA hospitals or other federal jurisdictions. NRC would retain authority, but in essence, contract with the states to supplement NRC staff.

Delegated Program

Advantages

One entity develops and publishes rules. Rules become more uniform across the country and the process is more streamlined. Likewise, greater consistency in training and interpretation of rules results. This especially benefits licensees with facilities in multiple jurisdictions. Those companies would hold a single NRC license for multiple locations in the U.S.

One entity has comprehensive understanding of the National Materials Program, and Congress and licensees may turn to the program when seeking the national perspective.

A Delegated Program provides an alternative solution to a funding problem states experience when they start their Agreement programs. States wishing to become Agreement States find it difficult to get personnel trained and programs in place once a letter of intent has been signed by their governor. States have historically requested funding or “seed money” to get their programs started. NRC has not provided such funding in the past. Under a delegated program contract for certain types of licensees, state personnel could be trained by NRC staff. This could also be used by NRC as a mechanism for encouraging states to develop regulatory programs.

Disadvantages

Responsibility for public health and safety related to radiation control moves from state-level to federal-level. It is unlikely that states would voluntarily give its authority to a federal entity. States have no authority to regulate radioactive material within their borders unless delegated to them.

The number of states signing contracts may vary from year to year.

A single regulatory entity makes it more difficult to address regional needs.

Variability in licensing and inspection techniques will occur. Assessing federal reimbursement to states for resources used to implement delegated duties may vary. Variations occur based on the number and types of licensees and cost of living factors in different areas of the country.

Delegated Program

1. Roles and Responsibilities of NRC and States for Each Program Element

A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

States

States no longer have authority to license the use of radioactive materials within their borders. If a state participates in a delegated program for licensing, the state is required to evaluate applications in accordance with NRC's procedures. The state does not issue state licenses, but NRC licenses.

NRC

NRC has authority to license all uses of radioactive material in the U.S. NRC can delegate licensing activities to states that have requested to participate in such a program. This delegation may include the entire suite of licensing activities, or may apply only to certain types of licenses (such as specifically and generally licensed gauges).

It would not be cost effective to train staff in three different states to regulate low-level waste disposal; therefore, the NRC would probably not delegate these programs.

It would not be cost effective to train staff in four different states to regulate uranium recovery facilities; therefore, the NRC would probably not delegate these programs.

NRC may delegate monitoring of decommissioning activities and verification surveys at decommissioned sites; however, final approval of decommissioning is the responsibility of the NRC.

Delegated Program

B. Performing Materials Inspections

States	NRC
States would no longer have authority to inspect the use of radioactive materials within their borders. If a state participates in a delegated program for inspection, the state must inspect according to NRC's procedures. The state would not have any enforcement authority.	NRC has the authority to inspect all uses of radioactive material in the U.S. NRC can delegate inspection activities to states. This delegation may include the entire suite of licensed activities, or may apply only to certain types of licensees (such as specifically and generally licensed gauges).

C. Incidents/Allegations

States	NRC
Response to incidents would be dependent on delegated authority.	NRC may delegate the response to incidents within states, but would probably retain responsibility for responding to allegations.

D. Materials Licensing Guidance, Inspection Guidance and Rulemaking

States	NRC
States would not be required or allowed to develop guidance or rules. If a state determined that guidance was needed, they must ask NRC to take action.	NRC would be responsible for developing and publishing licensing and inspection guidance and rules. NRC may wish to ask states for input on these products, based upon the state’s experience.

Delegated Program

E. Training, Qualifications and Experience Standards for Regulatory Personnel

States
Each state is responsible for tracking training their own staff. States must make sure that qualified individuals perform delegated activities under the contract.

NRC
Because NRC has authority to regulate the use of radioactive material, NRC must ensure staff has received adequate training. This includes NRC staff and staff in states with delegated duties as well.

2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

This Option allows for any existing or future federal entity to run a National Materials Program. The entity is NRC for purposes of this comparison.

The roles of NRC and states changes from co-regulators to an employer/contractor relationship. NRC, as the federal entity, establishes regulation for the use, storage and transfer of radioactive material as well as guidance for licensees. NRC has responsibility for performing license reviews, issuing licenses and performing inspections. States or territories can "contract" with the NRC to perform license reviews and/or inspections for certain categories of licenses, according to NRC's procedures. NRC maintains enforcement authority. NRC collects fees from licensees. States receive training and funding to fulfill terms of the contract. NRC performs activities in states/jurisdictions that have not assumed delegated duties.

3. Are Statutory Changes Required for this Option?

The AEA would need to be revised to delete Agreement State program authority, and allow delegated program authority. States may need to modify their legislation in order to participate in a delegated program**.** NRC currently regulates only AEA material, but this Option requires changes to the AEA, and the scope of radioactive materials covered by the AEA could be modified at that time to include NARM.

4. What Coordination is Required?

Coordination would be needed to make sure states are meeting contract obligations and to provide instruction to NRC Regions and delegated states.

Delegated Program

5. Resources Needed and Who Pays?

Licensees would pay fees that would offset the expenses in states with delegated duties. States could try to supplement their contracts by charging fees for duties such as incident response or performing additional inspections when there has been a problem at a facility.

The following table compares the current NRC program resources and NRC resources to be expended if all 50 states participate in a Delegated Program. The estimate assumes 1) states would be responsible for implementing NRC's licensing, inspection and incident response functions, and 2) NRC does not delegate regulatory activities at uranium recovery and low-level radioactive waste facilities.

Figure 3.5 - NRC Resources for Current Program and Delegated Program

Activity	Current Program Costs* $ in millions	Current Program Costs* FTE	Delegated Program $ in millions	Delegated Program FTE
NMSS, Regions	$ 26.6	197	$ 38.7	149
Direct Support**	$ 10.0	63	$ 18.8	143
Agency Overhead***	$ 18.4	76	$ 18.5	76
Total	$ 55.0	336	$ 76.0	368

Source: NRC's FY 2001 budget - These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section

* Costs are the sum of contract support, travel costs and staff salaries and benefits.

** These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

*** These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

The changes in FTE from the Current Program in NMSS and the regions are a result of NRC's decreased effort in licensing and inspection activities. The resources necessary to write rules, guidance and procedures would remain the same as the Current Program. Additional resources would be necessary to administer the contracts associated with a delegated program.

Delegated Program

6. Accountability

NRC would be responsible for making sure that all delegated programs were functioning as specified in contracts and that the "national" program was meeting the NRC's strategic goals.

7. Program Assessment

Program reviews are conducted and frequency corresponds with the contract expiration date. If a program has not performed its duties according to the terms of the contract, the contract will not be renewed. There may be some provisions for terminating a contract if there are significant health and safety concerns.

8. Program Gaps

If the AEA is amended to incorporate discrete NARM, as recommended by the Working Group and stakeholders, the Working Group does not envision any program gaps other than the regulation of diffuse naturally-occurring radioactive material.

Single Regulatory Agency

A Single Regulatory Authority, NRC, becomes the pre-eminent regulator of radioactive materials covered under the Atomic Energy Act. NRC seeks authority to regulate NARM materials in discrete form for a more comprehensive radiation regulatory program as stakeholders suggested in a meeting in Arlington, Texas.

What are the roles/responsibilities of the NRC for each program element?	NRC reassumes regulatory responsibility in former Agreement States and assumes the role as the single regulator for all radioactive material. This Option assumes NRC obtains authority for NARM. NRC interacts primarily only with its licensees and stakeholders. There would be few direct interactions with states or state organizations over regulatory issues.
What are the roles/responsibilities of an Agreement State for each program element?	States have no regulatory responsibility for radioactive materials. They retain responsibility for regulating other sources of ionizing radiation.
Are statutory changes required?	Yes, the Agreement State Program must be eliminated from the AEA. Agreements need to be abrogated on a individual basis. NRC would need NARM authority to establish a comprehensive national materials program. States need to enact legislation to exclude AEA and NARM, yet retain authority for other sources of radiation.
What coordination is required?	An extensive federal and state effort is necessary to revise AEA. Substantial stakeholder involvement is required at both state and federal levels. An equally extensive effort is needed to abrogate each agreement under revised statutes and to convert state licenses to NRC licenses.
What resources are needed (federal and state)? Who would pay?	Present and future NRC licensees pay all program costs. The significant heavy cost of conversion becomes an "equity issue" for present NRC licensees. New licensees coming under NRC's regulatory authority could object to paying for the transition. NRC would also fully fund infrastructure to support its national program. States pay nothing, except for their costs to change legislation and terminate agreements.
Accountability	NRC accountability is similar to the Current Program. State accountability is similar to the Current Program, but only for diffuse naturally-occurring radioactive material.
Program Assessment	NRC needs to develop a new assessment program that would focus its evaluation on regional activities. IMPEP could be used as a model.
Program Gaps	AEA would need to be amended to include NARM. The only gap regarding radioactive materials would be diffuse NORM.

Single Regulatory Agency

Advantages

If NRC has authority to regulate NARM, it provides an immediate framework for a centralized National Materials Program.

In a centralized operation, the rulemaking, policy, guidance and decision making process would be less encumbered. NRC would not have to rely upon, or ask for states opinions or take into account their regulatory experience when conducting business. NRC would only have to be responsive to stakeholders, standards development organizations and the public.

While little direct savings would accrue from this “improved” process, states would no longer participate, thus saving some time and effort. The issue of compatibility of rules would be moot; the only applicable rules would be those enacted by NRC.

Disadvantages

To maintain an effective program and provide reasonable service to its stakeholders, NRC would need to redesign its existing structure.

NRC will take regulatory authority over approximately 15,000 licensees in the continental United States. In the mid-1990's, when NRC licensed approximately 6-7,000 licensees, NRC decreased from five Regions to four to accommodate a changing business environment. As the Single Regulatory Agency, NRC must devise ways to service the additional territory and licensees from the former Agreement States. Agreement States currently regulate about three times as many licensees as NRC (15,000 to 5,000). One option for NRC is to increase the number of Regional offices. Another set of options, such as the use of satellite offices, or extensive work-at-home arrangements could be employed. Another idea, expressed by one stakeholder, would be to establish an NRC office in each State. The administrative costs for such a large organization would be much more expensive than the Current Program.

NRC would be faced with an immediate need to increase the size of its management, professional and support staff and infrastructure. Cost of initial efforts are expected to be proportional to the number of existing licensees.

The extensive Agreement State knowledge base would be quickly dissipated and lost with this Option.

Single Regulatory Agency

Advantges - cont'd

A stakeholder pointed out that having a single license issued by a national entity would be preferable to the present system where a licensee has to have several licenses or have reciprocity recognition from different regulators. Manufacturers and distributors of sources and devices expect positive benefits because only one license would be required. Reconsolidating NRC's regulatory authority and including NARM could improve a discordant business environment, especially businesses whose activities cross regulatory boundaries.

Stakeholders believe that the cost of business would be lower and more consistent if radiation regulatory activities were administered by a single regulator. On average, the costs to licensees would decrease due to an economy of scale. Costs of a re-unified regulatory program would be shared by a much larger licensee base.

Additional cost savings would be realized only for states in the areas of rulemaking, guidance and policy because single, national rules, guidance and policy would need to be developed instead of those for 32 individual states.

Disadvantages - cont'd

Some state programs are heavily subsidized by state general revenue funds. If the cost of a reunified program is passed on to those licensees, they may actually see an increase in fees.

Single Regulatory Agency

1. Roles and Responsibilities of NRC and States for Each Program Element

Under this Option, only NRC has responsibility for addressing radiation protection program elements. There would be no change from NRC's current procedures, but there would be significant changes to the size of NRC's program.

NRC's role and responsibility remains the same as it was prior to the amendment of the AEA that permitted the development of Agreement States. Currently, NRC has relinquished its regulatory authority in 32 states. The change from the current program to a Single Regulatory Agency could be made voluntarily or required by legislation.

2. Are Statutory Changes Required for this Option?

A revision of the AEA to eliminate the Agreement State Program and for NRC to assume responsibility for regulating discrete NARM sources would be needed.

To terminate the Agreement State program through legislation, Congress would need to amend the AEA. NRC would abrogate the existing agreements, thus restoring NRC as the single regulator for AEA materials. Some states could object to any change to the AEA that would eliminate what they believe to be their highly successful state run radiation protection programs.

Although some states favor having NRC assume control over discrete NARM to further the development and consistency of a National Materials Program, this belief may not be universally held. Some Agreement States believe that they are already regulating both AEA and NARM in a consistent manner. What is needed, they believe, is for a more comprehensive process that would regulate similar risks from dissimilar materials in a like manner.

3. What Coordination is Required?

To voluntarily reassume its role, NRC would cancel its existing agreement with each Agreement State, likely spending considerable time and funds explaining the need to reverse the current program. NRC would need to obtain some form of consensus among the states, business, and the public. Thereafter, a smooth transition would result only if all existing Agreement States would readily agree to abandon each of their agreements with NRC. Should one or more Agreement States disagree with NRC's proposal, legal action would be likely. An individual state or a group of states could sue to prevent NRC's proposed change in the Agreement State program. The result would be a period of disharmony not conducive to operating an effective regulatory program.

Single Regulatory Agency

4. Resources Needed and Who Pays?

NRC licensees will fully fund the program unless Congress authorizes greater “off fee base” funding for certain aspects of a National Materials Program. Former Agreement States will have no responsibility for operating or funding a regulatory program. Although costs of the larger, nationalized program would be shared among the larger licensee base, it is unlikely that the licensees would see a marked decrease in fees from the present level. It's equally likely that fees may increase substantially. Increases would be needed to increase infrastructure and staffing, train more staff in licensing and inspection, increase management to support the increase in staff, and the increased costs for renting, leasing or buying more facilities to support a presence throughout the U.S. These increases could be necessary to support NRC in assuming authority for licensees formerly under Agreement State control.

For former Agreement State licensees, little change may occur because states tend to include NARM and AEA materials under a single license.

A Single Regulatory Agency assumes that NRC would implement a program sufficient to regulate all radioactive material in the US. The total number of AEA materials licenses in the US is approximately 20,000. NRC’s current resources in the materials arena would need to increase fourfold. Costs for regulating discrete NARM have not been included in these estimates because the bulk of the impact is in the increase in number of licenses from Agreement States, and those licenses treat NARM and AEA material in a similar manner. NRC resource implications are given in Figure 3.6 on the following page.

Single Regulatory Agency

Figure 3.6 - NRC Resources for Current Program and Single Regulatory Entity

Activity	Current Costs* $ in million	Current Costs* FTE	Single Regulatory Costs* $ in million	Single Regulatory Costs* FTE
NMSS, Regions	$ 26.6	197	$ 57.4	456
Direct Support**	$ 10.0	63	$ 14.8	120
Agency Overhead***	$ 18.4	76	$ 40.8	168
Total	$ 55.0	336	$113.0	744

* These resource estimates are based on NRC's FY 2001 budget and used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.

** Resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

*** Resources include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

5. Accountability

NRC would be accountible for all radioactive material uses in the United States. States would only be accountable for other ionizing radiation.

6. Program Assessment

Agreement States would not exist as NRC assumed its prior authority; therefore, program assessment is not required under this option. NRC may, if it chooses to do so, institute a self-assessment of programs and quality assurance to assure consistency between its offices nationwide.

7. Program Gaps

If NRC assumes responsibility for NARM, most gaps in a National Materials Program are eliminated.